

and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(2) It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 524.2101 Selenium disulfide suspension.

(a) *Specifications.* The product contains 0.9-percent weight in weight (w/w) selenium disulfide (1-percent weight in volume (w/v)).

(b) *NAS/NRC status.* These conditions are NAS/NRC reviewed and found effective. NADA's for similar products for these conditions of use need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(c) *Sponsors.* See 015563, 017135, 023851, and 050604 in § 510.600(c) of this chapter.

(1) *Indications for use.* For use on dogs as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and non-specific dermatoses.

(2) *Amount.* One to 2 ounces per application.

(3) *Limitations.* Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if rash or irritation develops, discontinue use and consult a veterinarian.

[47 FR 53351, Nov. 26, 1982, as amended at 48 FR 32762, July 19, 1983; 54 FR 36962, Sept. 6, 1989; 56 FR 9623, Mar. 7, 1991; 58 FR 41025, Aug. 2, 1993]

§ 524.2140 Squalane, pyrethrins and piperonyl butoxide.

(a) *Specifications.* The drug contains 25 percent squalane (hexamethyltetracosane), 0.05 percent pyrethrins and 0.50 percent technical piperonyl butoxide.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of ear mites in dogs and cats.

(2) It is administered as follows: Cats and dogs 5-15 pounds body weight, 4 to 5 drops in each ear daily. Dogs 16-30 pounds body weight, 5 to 10 drops in each ear daily. Dogs 30 pounds body weight and over 10 to 15 drops in each ear daily. The recommended treatment is for 7 to 10 days with repeated treatment in 2 weeks if necessary.

§ 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate (2-naphthyl-*N*-methyl-*N*-(3-tolyl) thionocarbamate) in an anhydrous cream base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypseum* in dogs and cats.

(2) A small amount of the cream is applied to the affected areas once or twice a day for 2 to 4 weeks. The areas to be treated are first cleared of exudate and the hair clipped if the areas are not already denuded. The cream is massaged into each lesion and immediate surrounding area until the cream is no longer visible.

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(3) If no response is seen after 2 weeks of treatment with the drug the diagnosis should be reviewed.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 29289, July 7, 1978, as amended at 52 FR 7833, Mar. 13, 1987]

§ 524.2481 Triamcinolone acetonide cream.

(a) *Specifications.* Triamcinolone acetonide cream contains 0.1 percent triamcinolone acetonide in an aqueous vanishing cream base.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use on dogs as an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

(2) The drug is applied by rubbing into affected areas two to four times daily for 4 to 10 days.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a)(1) *Specifications.* The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) *Sponsor.* See No. 000514 in § 510.600(c) of this chapter.

(b)(1) *Specifications.* The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is used as an aid in the treatment of external wounds and assists healing by facilitat-

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ing the removal of necrotic tissue, exudate and organic debris.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 56307, Dec. 28, 1976; 50 FR 9800, Mar. 12, 1985; 54 FR 25565, June 16, 1989; 56 FR 37474, Aug. 7, 1991]

§ 524.2640 Tylosin, neomycin eye powder.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in cattle for the treatment of pinkeye (infectious keratoconjunctivitis).

(2) It is administered by holding the eyelids open and dusting powder into both eyes. The treatment is repeated daily for up to 7 days depending on the severity of the infection. Affected animals should be protected from direct sunlight, dust, and flies. In an affected herd, all animals with or without signs of the disease should receive at least one treatment.

(3) If there is severe eye damage or if the condition persists or increases, discontinue administering the drug and consult a veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994]